

WHAT IS CLAIMED IS:

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1. A stimulation trials hypothalamic obesity probe for stereotactic placement in the hypothalamus of a patient, comprising:

at least one electrode support shaft, each of said at least one electrode support shafts having a plurality of stimulation electrodes, each of said plurality of stimulation electrodes electrically coupled to an electrical stimulation device for transmitting electrical signals to each of said plurality of stimulation electrodes, and each of said plurality of stimulation electrodes capable of independently outputting electrical discharges to the hypothalamus; and

a macrocatheter for housing said at least one electrode support shaft, said macrocatheter including a magnetic unit for magnetic stereotactic placement of said macrocatheter to a location adjacent to the hypothalamus.

2. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein said macrocatheter includes a magnetic unit located at the distal end of said macrocatheter.

3. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein said at least one electrode support shaft comprises a plurality of electrode support

shafts such that said hypothalamic obesity probe is capable of mapping the hypothalamus of an obesity patient following a single surgical procedure.

4. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein each of said plurality of stimulation electrodes functions as a monopolar stimulation electrode.

5. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein each of said plurality of stimulation electrodes functions as a bipolar stimulation electrode.

6. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein each of said plurality of stimulation electrodes is capable of independently outputting electrical discharges of low frequency and each of said plurality of stimulation electrodes is further capable of independently outputting electrical discharges of high frequency.

7. The stimulation trials hypothalamic obesity probe as claimed in claim 1, wherein each of said plurality of stimulation electrodes is capable of independently

outputting electrical discharges over a frequency range of from about 10 Hz to about 400 Hz.

8. A drug infusion assembly for microinfusing a drug into the hypothalamus, comprising:

at least one microinfusion catheter, each of said at least one microinfusion catheters for placement in the hypothalamus, each of said at least one microinfusion catheters having a plurality of drug delivery ports, each of said plurality of drug delivery ports for delivering a drug to a separate site within the hypothalamus, and each of said plurality of drug delivery ports capable of independent control;

a macrocatheter for housing said at least one microinfusion catheter;

a drug delivery manifold, each of said at least one microinfusion catheters functionally coupled to said drug delivery manifold;

a drug supply line functionally coupled to said drug delivery manifold; and

a drug reservoir/pump for retaining and pumping a drug, said drug reservoir/pump functionally coupled to said drug supply line.

9. The drug infusion assembly as claimed in claim 8, wherein said macrocatheter includes a magnetic unit, said magnetic unit for stereotactic placement of said macrocatheter to a specific location within the brain.

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B2 10. The drug infusion assembly as claimed in claim 8, wherein said macrocatheter includes a magnet located at the distal end of said macrocatheter.

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11. The drug infusion assembly as claimed in claim 8, wherein said at least one microinfusion catheter comprises a plurality of microinfusion catheters.

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12. The drug infusion assembly as claimed in claim 8, wherein said drug reservoir/pump is capable of pumping a drug at a variable rate.

✓ 13. The drug infusion assembly as claimed in claim 8, wherein said drug reservoir/pump is capable of pumping a drug at a variable rate, and the variable rate can be controlled percutaneously by a radio control unit.

✓ 14. The drug infusion assembly as claimed in claim 8, wherein said drug reservoir/pump includes a recharge valve for recharging said drug reservoir/pump with a drug.

✓ 15. The drug infusion assembly as claimed in claim 14, wherein said recharge valve is accessible percutaneously.

Sub 7 16. A method for treating an obesity patient by outputting electrical discharges from a hypothalamic obesity probe to selected portions of the patient's hypothalamus, comprising the steps of:

5 a) obtaining a three dimensional digital image of the patient's brain, the image showing the position of the hypothalamus;

b) inserting a macrocatheter adjacent to the hypothalamus;

10 c) inserting at least one electrode support shaft into the hypothalamus, wherein the at least one electrode support shaft bears a plurality of stimulation electrodes, the plurality of stimulation electrodes arranged longitudinally, and each of the plurality of stimulation electrodes being capable of independent control;

d) outputting electrical discharges from at least one of the plurality of stimulation electrodes, thereby stimulating at least one neuron in the hypothalamus;

15 e) monitoring the clinical effect or clinical effects of said step d) in order to determine those particular stimulation electrodes of the plurality of stimulation electrodes which will provide a clinically useful effect; and

f) delivering electrical discharges from those particular stimulation electrodes of the plurality of stimulation electrodes determined in said step e) to provide a clinically useful effect.

17. The method for treating an obesity patient as claimed in claim 16, wherein said step b) comprises introducing the macrocatheter via an introducer tube through a burr hole formed in the patient's cranium, and said step b) further comprises magnetic stereotactic placement of the macrocatheter adjacent to the hypothalamus, the magnetic stereotactic placement under computer control.

18. The method for treating an obesity patient as claimed in claim 16, wherein said step c) comprises inserting a plurality of electrode support shafts within the hypothalamus, each of the plurality of electrode support shafts bearing a plurality of longitudinally arranged stimulation electrodes, whereby a multitude of target areas of the hypothalamus can be sampled following a single surgical procedure.

19. The method for treating an obesity patient as claimed in claim 16, wherein said step f) comprises delivering electrical discharges from a hypothalamic obesity probe which is programmable for the chronic output of suitable electrical discharges from those particular stimulation electrodes determined to provide a clinically useful effect.

20. The method for treating an obesity patient as claimed in claim 16, wherein the electrical discharges outputted in said step d) and the electrical discharges delivered in said step f) have a frequency ranging from about 10 Hz to about 400 Hz.

21. The method for treating an obesity patient, as claimed in claim 16, wherein said step c) comprises inserting at least one electrode support shaft into the hypothalamus, wherein the at least one electrode support shaft bears a plurality of longitudinally arranged stimulation electrodes, each of the plurality of stimulation electrodes being a monopolar stimulation electrode or a bipolar stimulation electrode.

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22. A method for treating an obesity patient by microinfusing a drug into one or more selected portions of the hypothalamus of a patient, comprising the steps of:

- a) obtaining an image of the hypothalamus of the patient;
  - b) inserting a macrocatheter into the patient's brain adjacent to the hypothalamus, the macrocatheter housing at least one microinfusion catheter, and each of the at least one microinfusion catheters including a plurality of independently controllable drug delivery ports;
  - c) inserting the at least one microinfusion catheter into the hypothalamus;
  - d) sequentially infusing a drug from various members of the plurality of drug delivery ports on the at least one microinfusion catheter into corresponding sites of the hypothalamus proximate the various members of the plurality of delivery ports;
  - e) monitoring the clinical effect of said step d) in order to determine which of the various members of the plurality of drug delivery ports will provide a useful clinical result;
- and

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f) delivering a drug from those selected members of the plurality of drug delivery ports determined in said step e) to provide a useful clinical result.

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23. The method for treating an obesity patient according to claim 22, wherein said step b) comprises inserting the macrocatheter via an introducer tube inserted into a burr hole in the patient's cranium.

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24. A method for treating an obesity patient by electrical stimulation of the hypothalamus of the patient, comprising the steps of:

a) providing a three dimensional digital image of the patient's brain in order to indicate the precise location of the hypothalamus;

b) forming a burr hole at an appropriate location in the patient's cranium;

c) inserting an introducer tube into the burr hole;

d) introducing a macrocatheter into the introducer tube, wherein the macrocatheter includes at least one electrode support shaft having a plurality of stimulation electrodes, the plurality of stimulation electrodes arranged longitudinally on the at least one electrode support shaft;

e) inserting the macrocatheter in a zone of the patient's brain adjacent to the hypothalamus;

f) inserting the at least one electrode support shaft into the hypothalamus;



g) electrically stimulating at least one neuron in the hypothalamus by means of  
15 electrical discharges outputted from one or more of the plurality of stimulation electrodes;

h) monitoring the clinical effect of step g) to define regions of the hypothalamus  
which will provide a desired clinical result when electrical discharges are outputted thereto;  
and

i) outputting electrical discharges to regions of the hypothalamus defined in said  
20 step h).

25. The method for treating an obesity patient as claimed in claim 24, wherein said  
step e) comprises inserting a macrocatheter having a magnetic unit secured to the distal end  
thereof.

26. The method for treating an obesity patient as claimed in claim 24, wherein said  
step e) comprises magnetic stereotactic placement of the macrocatheter in a zone of the  
patient's brain adjacent to the hypothalamus, and the magnetic stereotactic placement of the  
macrocatheter is performed under computer control.

27. A method for treating an obesity patient by chronic electrical stimulation of  
the hypothalamus of the patient, comprising the steps of:

a) obtaining a three dimensional digital image of a patient's brain showing the location of the hypothalamus;

5 b) inserting a macrocatheter into a zone of the patient's brain adjacent to the hypothalamus, wherein the macrocatheter houses at least one electrode support shaft, and each of the at least one electrode support shafts has a plurality of stimulation electrodes, and each of the plurality of stimulation electrodes is capable of independently outputting electrical discharges of various frequencies;

10 c) inserting the at least one electrode support shaft into the hypothalamus of the patient;

d) delivering electrical discharges of various frequencies from a first set of the plurality of stimulation electrodes to a first set of neurons within the hypothalamus;

15 e) delivering electrical discharges of various frequencies from at least one further set of the plurality of stimulation electrodes to at least one further set of neurons within the hypothalamus;

f) monitoring the clinical effects of said steps d) and e) on appetite regulation by the patient, in order to determine the clinical effects of various combinations of electrical discharge frequency/location of stimulation electrodes;

20 g) optimizing the electrical discharges delivered to the neurons within the hypothalamus, according to steps d) and e), to provide optimum appetite regulation by the patient; and

h) programming the hypothalamic obesity probe for chronic delivery of electrical discharges of defined frequency and at specific locations within the hypothalamus, as  
25 determined in step g), to provide optimum appetite regulation by the patient.

28. The method for treating an obesity patient according to claim 27, wherein each of the plurality of stimulation electrodes is capable of independently outputting electrical discharges of various frequencies.

29. The method for treating an obesity patient according to claim 27, wherein each of the plurality of stimulation electrodes is capable of independently outputting electrical discharges at any given frequency over the range of from about 10 Hz to about 400 Hz.

30. The method for treating an obesity patient according to claim 27, wherein said step g) includes optimizing both the frequency of the electrical discharges over a frequency range from about 10 Hz to about 400 Hz, and the first set or the at least one further set of the plurality of stimulation electrodes from which the electrical discharges are outputted.

31. The method for treating an obesity patient according to claim 27, wherein the first set and the at least one further set of the plurality of stimulation electrodes from which

the electrical discharges are outputted each correspond to specific regions within the hypothalamus.

32. A method for electrically stimulating the hypothalamus of an obesity patient, comprising the steps of:

a) obtaining a three dimensional image of a patient's brain, the three dimensional image showing the location of the hypothalamus;

5 b) inserting a macrocatheter into a zone of the patient's brain, wherein the zone is adjacent to the hypothalamus, wherein the macrocatheter houses at least one electrode support shaft, each of the at least one electrode support shafts having a plurality of stimulation electrodes, and each of the plurality of stimulation electrodes capable of independently outputting electrical discharges, the electrical discharges of low frequency or  
10 of high frequency;

c) inserting the at least one electrode support shaft into a selected first region of the hypothalamus;

d) stimulating, by means of electrical discharges outputted from the plurality of stimulation electrodes, neurons in the selected first region of the hypothalamus;

15 and

e) monitoring clinical effects of said step d).

33. A method for treating an obesity patient by placing a chronic electrical stimulator into the hypothalamus of the patient, comprising the steps of:

a) obtaining a three dimensional image of a patient's brain, the three dimensional image showing the location of the hypothalamus;

5 b) inserting a macrocatheter into a zone of the patient's brain, wherein the zone is adjacent to the hypothalamus, wherein the macrocatheter houses at least one electrode support shaft, each of the at least one electrode support shafts having a plurality of stimulation electrodes, and each of the plurality of stimulation electrodes capable of independently outputting electrical discharges, the electrical discharges of low frequency or  
10 of high frequency;

c) inserting the at least one electrode support shaft into a selected first region of the hypothalamus;

d) stimulating, by means of electrical discharges outputted from the plurality of stimulation electrodes, neurons in the selected first region of the hypothalamus;

15 e) monitoring clinical effects of said step d);

f) after said step e), reinserting the at least one electrode support shaft into a selected additional region of the hypothalamus;

20 g) stimulating, by means of electrical discharges outputted from the plurality of stimulation electrodes, neurons in the selected additional region of the hypothalamus;

h) monitoring clinical effects of said step g);

i) repeating steps f) through h) until a satisfactory clinical effect is obtained;

and

j) implanting the chronic electrical stimulator in an appropriate region of

25 the hypothalamus.

34. The method for treating an obesity patient by placing a chronic electrical stimulator into the hypothalamus of the patient as claimed in claim 33, wherein said step j) comprises implanting in an appropriate region of the hypothalamus a chronic electrical stimulator which has been programmed to duplicate the satisfactory clinical effect as  
5 obtained in said step i).

35. A method for treating an obesity patient by infusion of a drug from a drug infusion assembly into the hypothalamus of the patient, the method comprising the steps

of:

a) obtaining a three dimensional image of a patient's brain, the three

5 dimensional image showing the location of the hypothalamus;

b) inserting a macrocatheter into a zone of the patient's brain, wherein the zone is adjacent to the hypothalamus, wherein the macrocatheter houses at least one microinfusion catheter, each of the at least one microinfusion catheters having a plurality

of drug delivery ports, and each of the plurality of drug delivery ports capable of  
10 independently outputting a drug, the drug capable of activating or deactivating neurons in  
one or more regions of the hypothalamus;

c) inserting the at least one microinfusion catheter into a selected first  
region of the hypothalamus;

d) infusing a quantity of a drug from at least one of the plurality of drug  
15 delivery ports to at least one neuron of the selected first region of the hypothalamus; and

e) monitoring clinical effects of said step d).

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36. The method for treating an obesity patient as claimed in claim 35, further  
comprising the steps of:

f) after said step e), reinserting the at least one microinfusion catheter into  
a selected additional region of the hypothalamus;

g) infusing a quantity of the drug from at least one of the plurality of drug  
5 delivery ports to at least one neuron of the selected additional region of the hypothalamus;

h) monitoring clinical effects of said step g); and

i) repeating steps f) through h) until a satisfactory clinical effect is obtained.

37. The method for treating an obesity patient as claimed in claim 36, wherein said step g) comprises adjusting the amount of drug infused from the at least one of the plurality of drug delivery ports.

38. A method for treating an obesity patient by infusion of a drug from a drug infusion assembly into the hypothalamus of the patient, the method comprising the steps of:

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- a) obtaining a three dimensional image of a patient's brain, the three dimensional image showing the location of the hypothalamus;
  - b) forming a burr hole at an appropriate location in the patient's cranium;
  - c) inserting an introducer tube into the burr hole;
  - d) introducing a macrocatheter into the introducer tube;
  - e) under magnetic stereotactic computerized control, inserting the macrocatheter into a zone of the patient's brain, wherein the zone is adjacent to the hypothalamus, wherein the macrocatheter houses at least one microinfusion catheter, each of the at least one microinfusion catheters having a plurality of drug delivery ports, and each of the plurality of drug delivery ports capable of independently outputting a drug, the drug capable of activating or deactivating neurons in one or more regions of the hypothalamus;
  - 15 f) inserting the at least one microinfusion catheter into a selected first region of the hypothalamus;



g) infusing a quantity of a drug from at least one of the plurality of drug delivery ports to at least one neuron of the selected first region of the hypothalamus; and

h) monitoring clinical effects of said step g);

i) after said step h), reinserting the at least one microinfusion catheter into a selected additional region of the hypothalamus;

j) infusing a quantity of the drug from at least one of the plurality of drug delivery ports to at least one neuron of the selected additional region of the hypothalamus;

k) monitoring clinical effects of said step j)); and

l) repeating steps i) through k) until a satisfactory clinical effect is obtained.

39. A method for treating an obesity patient by chronic electrical stimulation of the hypothalamus of the patient, the method comprising the steps of:

a) obtaining a three dimensional digital image of a patient's brain, the three dimensional image showing the location of the hypothalamus;

b) inserting a macrocatheter into a zone of the patient's brain adjacent to the hypothalamus, wherein the macrocatheter houses at least one electrode support shaft, each of the at least one electrode support shafts having a plurality of stimulation electrodes, and each of the plurality of stimulation electrodes capable of independently outputting electrical discharges of various frequencies;

c) inserting the at least one electrode support shaft into the hypothalamus;

d) delivering electrical discharges of various frequencies from a first set of the plurality of stimulation electrodes to a first set of neurons within the hypothalamus;

40 e) delivering electrical discharges of various frequencies from at least one further set of the plurality of stimulation electrodes to at least one further set of neurons within the hypothalamus;

f) monitoring clinical effects of said steps d) and e) on appetite regulation by the patient;

45 g) based on said steps d), e), and f), optimizing the electrical discharges delivered to the neurons within the hypothalamus for optimum appetite regulation;

h) based on said step g), pre-programming a chronic electrical stimulator for optimum clinical effectiveness in the patient; and

i) implanting the pre-programmed chronic electrical stimulator in the hypothalamus of the patient.

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